Amendments

In the Specification

Please add paragraph [0049]:

[0049] The present invention also encompasses a reagent comprising a fluid medium containing a first substrate having a first binding species attached thereto; and a second substrate having regions characterized by their ability to selectively bind said first biding species if dissociated from said first substrate and regions characterized by their ability to selectively bind first binding species associated with the first substrate. The second substrate binds a plurality of first binding species to a common second substrate and an aggregate is formed comprising the plurality of first substrate having first binding species attached thereto, cross-linked by the second substrate.

Objections

To the Specification:

The Examiner objected to the Specification as follows:

1. The Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter of claim 14 stating "a second substrate having . . . regions capable of selectively binding first binding species associated with said first substrate. To overcome the objection Applicants have added the substance of originally filed claim 14 to the specification at new paragraph 49.

2. The Examiner further objected to the Specification for informalities. The Examiner believes that the recitation of "Level" and "Levels" is indefinite stating that it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels".

Applicants submit that the term "Level" is adequately clear as used in the specification and in light of common knowledge to those of reasonable skill in the art. Table 1 shows that Levels as used in the specification refers to levels of a calibrator. A calibrator is a standard having a set amount of an analyte to be assayed. Here there are five different levels of calibrators, the first being 0, the second about 1 and the fifth about 60. For purposes of this invention the units of the level of calibrators are irrelevant. The purpose of the Table 1 and 2 and the experiments is to demonstrate the differences in recovery of the assayed calibrators over time in the absence and presence of the "scavenger" particles. As the term Level is used, it is clear to see that there are 5 different levels of calibrators.

Rejections

§112, Second Paragraph

Claims 12 and 14 were rejected as being indefinite. The Examiner states that the mechanism by which a "region" binds a binding species is not clear. Applicants traversed and provided examples of where in the specification the mechanisms for regions binding a binding region were listed. The Examiner found the arguments unpersuasive stating those paragraphs did not recite the term "region" or describe the mechanism. Applicants traverse. Paragraph [0021] and newly added paragraph [0049] (from claim 14) use the term "regions". Paragraphs [0023] and [0032] describes the mechanism of diffusion into pores, and paragraph 36 describes several other mechanisms.

§102 Rejections

1. The Examiner again rejected claim 1-8, 12 and 14-16 as being anticipated by Ullman et al. (US 6,406,913). The Examiner states that the amendment adding "capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength" does not structurally differentiate the invention form Ullman et al.

Applicants ask the Examiner to review the phrase as a whole. The second substrate has binding partners capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength.

The binding partners disclosed in Ullman et al. do not disclose or suggest that the partners selectively bind dissociated first binding species. In fact and to the contrary, Ullman et. al. at lines 33 to 34 state that preferably the photosensitizer and chemiluminescent molecules are incorporated into particles and the sbp (specific binding partner) members are attached to the particles. There is no selective binding of the binding partners in Ullman et al. to dissociated first biding species. The language in the claims describes the second substrate

and serves to distinguish the claims structurally from Ullman et al in much the same way as an antibody specific to hCG does not anticipate an antibody specific to cyclosporine. Thus, Applicants respectfully request that the rejection be withdrawn.

2. The Examiner also repeated the rejection relating to Ullman's describing cavities on the binding species stating that claim 7 does not contain require the material (substrate) to be permeable. The Examiner is correct in that statement – the substrate is not required to be permeable. Regardless, the Examiner stated that Ullman teaches cavities on the solid support (the "substrate") referring to Ullman et al. at col. 19 at about line 39. Applicants point is that Ullman is describing cavities on the binding material (e.g. the antibody or the like) NOT the solid support or substrate material. Col. 19, lines 36 to 43 states:

> *Specific binding – the specific recognition of one of two different molecules for the other compared to substantially less recognition of other molecules. Generally, the molecules have areas on their surfaces or in cavities giving rise to specific recognition between the two molecules. Exemplary of specific binding are antibody-antigen interactions, enzyme-substrate interactions, polynucleotide interactions, and so forth.*

Thus, Applicants respectfully request that the rejection be withdrawn.

3. In the prior action, the Examiner rejected claim 12 stating that Ullman et al. teach a reagent used in a sandwich assay comprising a first binding species (col. 37, lines 58+) wherein a first portion (col. 38, lines 7-9) is attached to the first substrate and a second portion is dissociated from the first substrate and the second portion binds to a second substrate. Applicants traverse. Applicants stated they have not found in Ullman et al. where it is disclosed that a second portion of the first binding species is dissociated from the first substrate and then binds to a second substrate. In this Final Office Action, the Examiner states that Ullman et al. describe a second portion of the first binding species (the beta subunit of TSH) that is dissociated from that substrate. Applicants point out that this is not a first portion of a first binding species and second portion of the first binding species. Instead, in this embodiment of Ullman et al. a first binding species (antibody for TSH) is covalently linked to a chemiluminescent molecule. See, Ullman et al. at col. 37, lines 58-60. At col. 37, line 64 to col. 38. line 5, it can be seen that a second binding species (a different antibody to TSH) is linked to a latex particle (col. 38, lines 3-5). The latex particle is also linked to rose Bengal (col. 37, line 64 to col. 38, line 3. Ullman et al. further distinguishes the two antibodies. One of the two antibodies recognizes the alpha subunit of TSH, the other antibody recognizes the beta subunit of TSH. The hormone TSH is comprised of the alpha unit of TSH linked to the beta unit of TSH

forming one molecule. Thus, when TSH is present in a sample, the TSH is sandwiched by the two different antibodies. There is simply no first portion of a binding species attached to a substrate and a second portion of the binding species dissociated from the substrate.

Thus, Applicants submit that the claims as amended are not anticipated by Ullman et al. and respectfully request that the rejections be withdrawn.

Applicants submit that the amendments and remarks overcome the Examiner's objections and rejections. The Examiner is encouraged to contact the undersigned if the Examiner has any matter that the Examiner would like to address.

Respectfully submitted,

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